

REMARKS

Reconsideration of this application is respectfully requested. Claims 20-37 are pending.

Claims 20-37 remain rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,943,590 (“Boegesoe”) in view of U.S. Patent No. 5,846,982 (“Audia”) and Schaller et. al., *J. Neuropsychiatry and Clin. Neurosciences*, 11(4):516, Fall 1999 (“Schaller”). The Examiner contends that Audia teaches that “attention deficit hyperactivity disorder (col. 53, line 7) can be treated with compounds that inhibit serotonin reuptake” (*see* Office Action, page 4). The Examiner further contends that Schaller teaches that ADHD increases one’s risk for major depression.^{*} *Id.* The Examiner concludes that it would have been obvious to a person of ordinary skill in the art to administer ADHD patients a selective serotonin reuptake inhibitor (“SSRI”), such as escitalopram as taught by Boegesoe, because both ADHD and depression are treatable by inhibiting serotonin reuptake.

Applicants respectfully traverse this rejection and request reconsideration.

The Examiner argues that Applicants cannot rely on Schaller as teaching away from the use of SSRIs for the treatment of ADHD because such definitive conclusions cannot be made based on a single case report and because Schaller is only relied upon to show that ADHD increases one’s risk for major depression (*see* Office Action, page 5). The Examiner also argues that there is no mention in Schaller that SSRIs are not effective at treating ADHD (*see* Office Action, page 6). Applicants respectfully submit that these position are not well founded.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, (Fed. Cir. 1983). *See* MPEP § 2141.01. As previously pointed out in Applicants’ March 6, 2007 response, the administration of sertraline, an SSRI, had absolutely no effect on the patient’s ADHD in Schaller. Schaller specifically states that after administration of sertraline (and clonazepam), “the patient still met the criteria for adult ADHD” (*see* Schaller,

col. 3, lines 4-6). The patient's ADHD symptoms did not improve until he was treated with methylphenidate, which is a stimulant. A person of ordinary skill in the art reading Schaller would therefore not have predicted that sertraline, *or any other SSRI*, would effectively treat ADHD as the one SSRI administered in Schaller failed to treat the patient's ADHD.

The Examiner previously noted that Schaller describes an "improvement" in the patient following treatment with sertraline. Applicants, however, pointed out that the "improvement" referred to by Schaller was in the patient's anxiety level as demonstrated by reference to a lower BAI score, and not in ADHD. "BAI," the Beck Anxiety Inventory score, is a measure of generalized anxiety and not a quantitative or qualitative measure of ADHD.

In sum, there is no teaching or suggestion by Schaller that administration of sertraline, much less any other SSRI, has any effect on ADHD. Rather, Schaller concludes that patients with co-morbidities of ADHD, major depression, and panic attacks "should have their [major depression] treated first, their anxiety disorder next, and finally be offered a non-combinational, low potency stimulant for ADHD" (*see* Schaller, abstract).

The Examiner further argues that "Applicant's arguments directed toward sertraline [the SSRI in Schaller] have nothing to do with the obviousness rejection since sertraline was not claimed" (*see* Office Action, pages 5-6). Applicants respectfully disagree. The fact that sertaline was ineffective at treating ADHD contradicts the purported teaching in Audia that any serotonin reuptake inhibitor can treat ADHD. Accordingly, Schaller's discussion of the efficacy of sertaline is pertinent to the obviousness inquiry.

Boegesoe and Audia fail to cure these defects. Boegesoe is silent with respect to the treatment of ADHD.

Audia does not disclose or suggest that *any* serotonin reuptake inhibitor can be used to treat ADHD. Rather, Audia only teaches that the tetrahydropyridinyl- and piperidinyl-indoles and benzothiophenes described therein are useful in treating ADHD. *See* Audia at col. 1, lines 46-50, and col. 52, lines 1-3. Escitalopram does not fall into any of these classes. Furthermore,

Audia does not teach or suggest that serotonin reuptake inhibitors as a general class can be used to treat ADHD. Even if, *arguendo*, Audia is interpreted as teaching that serotonin reuptake inhibitors in general are effective at treating ADHD (which is not admitted here), this broad proposition is contradicted by the clinical data in Schaller. Accordingly, a skilled artisan would understand that the teachings in Audia regarding ADHD only apply to the specific compounds described therein. Therefore, one of ordinary skill in the art would not have had any motivation to combine Audia with Boegesoe, as escitalopram is not in the structural class of compounds described in Audia.

For the foregoing reasons, Boegesoe, Audia, and Schaller, alone or in combination, fail to render claims 20-37 obvious. Therefore, Applicants respectfully request withdrawal of this rejection.

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes can be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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